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Copy Date 1-13-05
Publication Date 1-14-05
Certifier

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

# New Animal Drugs for Use in Animal Feeds; Melengestrol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for use of a melengestrol acetate liquid Type A medicated article to make Type C medicated feeds for heifers fed in confinement for slaughter and for heifers intended for breeding.

**DATES:** This rule is effective [*insert date of publication in the* **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov.*

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–343 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, a liquid Type A medicated article used to make dry and liquid Type C medicated feeds for heifers fed in confinement for slaughter and for heifers intended for breeding. Ivy Laboratories' HEIFERMAX 500 Liquid Premix is approved as a generic copy of Pharmacia and Upjohn Co.'s MGA 500 (melengestrol acetate) Liquid Premix, approved under NADA 39–402. The application is approved as of

cv0471

2005-200-343
2005-39-402

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December 3, 2004, and the regulations are amended in 21 CFR 558.342 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

■ 2. Section 558.342 is amended by revising paragraph (b) and in the table in paragraphs (e)(1)(i) and (e)(1)(ii) in the "Sponsor" column by adding in numerical sequence "021641" to read as follows:

**§ 558.342 Melengestrol.**

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(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 021641 for use of product described in paragraph (a)(2) of this section.

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Dated: 12/29/04

December 29, 2004.

SFS

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S